K002285

SEP 26 2000

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SUMMARY OF 510(K) SAFETY AND EFFECTIVENESS INFORMATION

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The ATAC PAK ALP Reagent Kit and the ATAC 8000 Random Access Chemistry System are intended for use as a system for the quantitative determination of alkaline phosphatase in serum and plasma. ALP results are used in the diagnosis and treatment of liver, bone, parathyroid, and intestinal diseases. The ATAC PAK ALP Reagent determines alkaline phosphatase through the enzymatic hydrolysis of p-nitrophenylphosphate. The resulting rate of increase in absorbance at approximately 405 nm is proportional to the alkaline phosphatase activity in the sample. The ATAC PAK ALP Reagent Kit is substantially equivalent to the Beckman Synchron ALP Reagent Kit, product no. 442670, which is currently marketed by Beckman Coulter Inc. of Brea California.

The effectiveness of ATAC PAK ALP Reagent Kit and the ATAC 8000 Random Access Chemistry System is shown by the following studies.

The recovery of alkaline phosphatase using the ATAC PAK ALP Reagent is linear from 10 to 1000 U/L in the primary usable range and from 900 to 2000 U/L in the hyperactive dilution range as shown by the recovery of linearity standards which span the respective ranges. For both ranges, the coefficient of determination (r^2) approaches 1.0, and the standard error of regression ($s_{y.x}$) is less than 1.5% of the upper limit of the claimed range. Regression statistics, which compare standard recoveries to standard dilution factors in both ranges, are shown below.

Primary Usable Range
range = 2 - 1049 U/L, $r^2 = 0.998$, $s_{y.x} = 14.5$ U/L, df = 49

Hyperactive Usable Range
range = 770 - 2077 U/L, $r^2 = 0.994$, $s_{y.x} = 34.1$ U/L, df = 49

Precision, using both the normal sample volume and the reduced sample volume with hyperactive dilution, is demonstrated by the replicate assay of commercially available serum controls. Precision statistics, calculated analogous to the method described in NCCLS Guideline EP3-T, are shown below.

Precision of ALP Recoveries in U/L

			Within Run		Total	
Sample	n	mean	1SD	%CV	1SD	%CV
Serum 1	45	40	1.5	3.9%	2.1	5.4%
Serum 2	48	244	4.3	1.8%	5.9	2.4%
Serum 3	48	570	10.1	1.8%	11.5	2.0%

Precision of ALP Recoveries in U/L using Hyperactive Dilution

			Within Run		Total	
Sample	n	mean	1SD	%CV	1SD	%CV
Serum 1	48	972	15	1.5%	23	2.3%
Serum 2	48	1336	20	1.5%	36	2.7%
Serum 3	48	1745	29	1.7%	39	2.3%

Mixed serum and plasma specimens, collected from adult patients, were assayed for alkaline phosphatase at 37°C using the ATAC 8000 Random Access Chemistry System and another commercially available method. Results were compared by least squares linear regression and the following statistics were obtained.

ATAC 8000 = 5.2 U/L + 1.033 x Competitive Reagent
r = 0.997 n = 310 range = 24 - 972 U/L

The detection limit claim of 10 U/L is documented through the repetitive assay of a diluted serum control. The observed detection limit, calculated as two standard deviations of a 30 replicate within run precision study, is 5.5 U/L and is below the claimed limit of 10 U/L.

The 10 day on board reagent stability claim is documented through the assay of serum controls over the claimed period. In all cases, the total imprecision estimates of alkaline phosphatase recoveries over the test period are less than 2 U/L or 2% for both the primary usable range and the extended hyperactive dilution range.

Wynn Stocking
Manager of Regulatory Affairs
Elan Diagnostics

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 26 2000

Mr. Wynn Stocking
Manager, Regulatory Affairs
Elan Diagnostics
231 N. Puente Street
Brea, California 92821

Re: K002285
Trade Name: ATAC PAK ALP Reagent
Regulatory Class: II
Product Code: CJE
Dated: July 24, 2000
Received: July 26, 2000

Dear Mr. Stocking:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K002285

Device Name: ATAC PAK ALP Reagent

Indications For Use:

The ATAC PAK ALP Reagent Kit and the ATAC 8000 Random Access Chemistry System are intended for use as a system for the quantitative determination of alkaline phosphatase (ALP) in serum and plasma. Alkaline phosphatase results are used in the diagnosis and treatment of liver, bone, parathyroid, and intestinal diseases.

This reagent is intended to be used by trained personnel in a professional setting and is not intended for home use.

Respectfully,

Wynn Stocking

Wynn Stocking
Regulatory Affairs Manager
Elan Diagnostics

24 July, 2000

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Carol Benson for Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K002285

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ____

(Optional Format 1-2-96)